

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

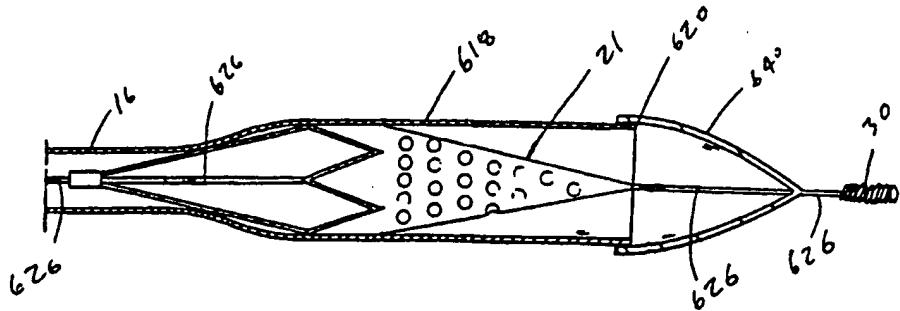
THIS PAGE BLANK (USPTO)



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61F 2/01		A1	(11) International Publication Number: WO 00/49970 (43) International Publication Date: 31 August 2000 (31.08.00)
(21) International Application Number: PCT/US00/04975 (22) International Filing Date: 24 February 2000 (24.02.00)		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(30) Priority Data: 09/256,865 24 February 1999 (24.02.99) US		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311 (US).			
(72) Inventors: DANIEL, John; 12705 48th Avenue North, Plymouth, MN 55442 (US). LOWE, Brian, J.; 232 Satellite Lane Northeast, Fridley, MN 55432 (US). CASSELL, Robert; 14398 91st Street Northeast, Otsego, MN 55330 (US). SLAKER, Bradley, F.; 5310 Salem Lane, Greenfield, MN 55357 (US). ARNOLD, John, E., Jr.; 2714 West 55th Street, Minneapolis, MN 55410 (US). BROOME, Thomas, E.; 511 Sunnyside Lane, Hopkins, MN 55343 (US).			
(74) Agents: SEAGER, Glenn, M. et al.; Crompton, Seager & Tufte, LLC, Suite 895, 331 Second Avenue South, Minneapolis, MN 55401 (US).			

(54) Title: INTRAVASCULAR FILTER AND METHOD



(57) Abstract

A filter disposed at the distal end of an elongate guidewire. Catheters are provided for delivering the filter to, and retrieving the filter from, a treatment site. The catheters can be over-the-wire or single operator exchange. The catheters include a housing for receiving the filter therein. The housing has an atraumatic distal end.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UC	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTRAVASCULAR FILTER AND METHOD

Related Applications

This application is related to U.S. Patent Application Serial No. 08/813,794, entitled "Distal Protection Device" and U.S. Patent Application Serial No. 09/035,740, entitled "Distal Protection Device and Method", both of which are incorporated herein by reference.

Background of the Invention

The present invention relates to the field of minimally invasive, percutaneous procedures such as angioplasty. In particular, the invention relates to a distal filter for use during such a procedure.

Angioplasty, atherectomy and stent placement, among other procedures, have become well accepted for treatment of coronary lesions. These procedures are often performed as an alternative to coronary bypass. It is also possible, however, that a saphenous vein graft, which is used to bypass coronary lesions, may itself develop a lesion. These lesions may also be treated by minimally invasive procedures such as angioplasty, atherectomy and/or stent placement.

When lesions are treated by these minimally invasive, percutaneous methods, it is possible that particles of plaque, thrombus or other material may break loose from the lesion and drift distally into the smaller coronary arteries. When these minimally invasive methods are performed on native arteries, the plaque or thrombus released during the procedure rarely cause embolization. When these procedures are performed on saphenous vein grafts, however, the

incidence of embolism due to the breaking off of plaque or thrombus from the vein graft is substantially greater than from native arteries.

The increased incidence of embolization is believed to be due, at least in part, to the larger diameter of the bypass graft relative to the native artery. The larger diameter of the graft results in a slower blood flow velocity through the graft than the native artery. In addition, the plaque and thrombus of vein grafts is somewhat more fragile than that found in native arteries.

As the difference in embolism associated with treatment of native arteries and vein grafts has been noted, it would be desirable to develop techniques to reduce embolism associated with treatment of vein graft lesions. Additionally, where stent placement or other minimally invasive treatments are performed on the carotid artery, it would be desirable to limit the drift of plaque and thrombus toward the brain.

Summary of the Invention

The present invention pertains to an intravascular filter for use during minimally invasive percutaneous procedures. The filter is preferably placed distally, within the blood stream, of the site of the interventional procedure. The filter may be used to filter plaque, thrombus and other debris released into the blood stream during minimally invasive procedures performed in blood vessels.

A filter assembly in accordance with the present invention includes a catheter including an elongate shaft having a proximal end and a distal end. A housing is disposed at the distal end of the shaft. The housing itself has a distal

end. An elongate wire extends at least in part through the catheter. The wire has a proximal end and a distal end. A filter is connected to the wire proximate the distal end of the wire. The filter, during delivery and retrieval from its deployment site is preferably at least, in part, disposed within the housing.

By retracting the catheter relative to the filter, the filter emerges from within the housing to a position outside the housing for deployment of the filter. When the filter is disposed outside the housing, the filter can be drawn into the housing by pushing the housing over the filter. It is preferable, however, to retrieve the filter with a different catheter having a housing having a larger inside diameter than the housing of the catheter used to deliver the filter.

It is preferable that the distal end of the housing be atraumatic. This can be accomplished by using a soft atraumatic material for the filter distal end. Additionally, if the catheter is a delivery catheter, the distal end can also be tapered by heat shrinking the distal end of the housing around a portion of the filter. The filter itself can also be slightly wider than the distal end of the housing such that the filter acts as an atraumatic distal end of the filter assembly. The distal end of the housing can also be rounded inwardly toward the filter. In yet another embodiment, the distal end of the housing can include an elastomeric sheath which tapers distally. In still another embodiment of the filter assembly, a collapsible shell can be connected to the wire. The shell is preferably disposed substantially distally of the filter. The wire can include a spring tip.

Where the catheter is a retrieval catheter, a housing atraumatic tip insert can be disposed within the housing and extend distally therefrom while the filter

is positioned outside the housing. The insert preferably tapers distally. In one embodiment, the insert can be releasably connected to the distal end of the housing. In a preferred embodiment, the insert includes a balloon. In yet another embodiment, the insert includes a flap which extends transversely over the distal end of the housing. When the filter is withdrawn into the housing, the insert is drawn proximally into the housing as well.

The elongate shaft of the filter assembly can have an elongate wire lumen running through its length. In such a configuration, the catheter can be considered an over-the-wire catheter. The catheter can be converted to a single operator exchange catheter by dividing the shaft into two or more elongate segments and coupling the segments together. The length of the segments should be such that they can be uncoupled or coupled as they are being withdrawn or advanced over the wire. The coupling could include a bayonet fastener or a threaded fastener for example. As an alternative to the coupling, the catheter can be configured for a single operator exchange by providing a telescoping or collapsible portion. The collapsible portion can include a member which can have a braided portion. In an alternate embodiment, the catheter can include longitudinal slits for removal of the catheter from the wire.

The filter itself is disposed at the distal end of the wire. The filter includes an expandable frame and filter membrane. The frame can include a nickel titanium alloy. The membrane preferably surrounds a portion of the wire and is configured to taper distally. The membrane preferably includes polyurethane and defines a plurality of apertures. Once the filter is deployed distally of the lesion to

be treated, the wire can be used as a guidewire for advancing angioplasty, atherectomy, or other devices thereover.

Brief Description of the Drawings

Figure 1 is a partial cross sectional side view of a delivery catheter and filter in accordance with the present invention;

Figure 2 is a partial cross sectional view of the catheter and filter of Figure 1 wherein the filter is advanced distally from the catheter;

Figure 3 is a view of a shaft of a catheter in accordance with the present invention including a collapsible portion;

Figure 4 is a view of the shaft of Figure 3 wherein the collapsible portion is collapsed;

Figure 5 is a view of an alternate embodiment of the filter in accordance with the present invention;

Figure 6 is a cross sectional view of the filter of Figure 5;

Figure 7 is a side view of the filter of Figure 5 disposed within a delivery catheter;

Figure 8 is a side view of the catheter and filter of Figure 7 rotated 90° about the longitudinal axis thereof;

Figure 9 is an alternate embodiment of a delivery catheter housing;

Figure 10 is a distal end view of the housing of Figure 9;

Figure 11 is yet another alternate embodiment of the delivery catheter housing;

Figure 12 is yet another alternate embodiment of the delivery catheter housing;

Figure 13 is yet another alternate embodiment of the delivery catheter housing;

Figure 14 is yet another alternate embodiment of the delivery catheter housing;

Figure 15 is a view of an alternate embodiment of a housing for a delivery catheter in accordance with the present invention and a collapsible shell disposed over the distal end of the housing;

Figure 16 shows the shell in a collapsed position;

Figure 17 is a partial cross sectional view of a retrieval catheter including a tip insert and filter;

Figure 18 is a view of the filter engaging the tip insert of Figure 17;

Figure 19 is a view of the insert and filter of Figure 17 withdrawn into the catheter;

Figure 20 is a partial cross sectional view of an alternate embodiment of a retrieval catheter, filter and retrieval catheter insert;

Figure 21 is a view of the alternate embodiment of the insert of Figure 20 partially withdrawn into the catheter.

Figure 22 is a partial cross sectional view of an alternate embodiment of a retrieval catheter, filter and retrieval catheter insert;

Figure 23 is a partial cross sectional view of an alternate embodiment of a retrieval catheter, filter and retrieval catheter insert;

Figure 24 is a view of a manifold for use with the embodiment of the retrieval catheter of Figure 23;

Figure 25 is a cross sectional view of the manifold of Figure 24 wherein the wire has been drawn proximally to withdraw the filter into the housing; and

Figure 26 is a cross sectional view of an alternate manifold in accordance with the present invention.

Detailed Description of the Invention

Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 is a partial cross sectional, side view of a filter assembly 10 in accordance with the present invention. Filter assembly 10 includes a delivery catheter 12. Delivery catheter 12 can include a proximal section 14 coupled to a distal section 16. Disposed at the distal end of catheter 12 is a filter housing 18. Filter housing 18 has a distal end 20. As known to those skilled in the art, a manifold having guide wire and side ports can be disposed at the proximal end of catheter 12.

Catheter 12 preferably defines a lumen 19 extending therethrough. In the region of housing 18, lumen 19 preferably has a diameter of between 2F to 5F and more preferably, between 3F to 4F and most preferably, about 3F. The diameter of lumen 19 in shaft sections 14 and 16 is preferably between 2F and 5F and most preferably, about 2F.

The length of the delivery catheter is preferably sufficient to reach a treatment site in a coronary artery or graft from a femoral approach. It can be

appreciated, however, that if an alternate approach such as a brachial approach is taken, or an alternative target site is desired, the length of the catheter should be appropriate to the specific use.

The catheter can be manufactured from any of the appropriate biocompatible materials from which one skilled in the art would be aware. Shaft portions 14 and 16 should be made from a material sufficiently rigid, yet flexible to be advanced through a tortuous path to a target site. Marker bands can be placed on catheter 12 to guide the placement of filter 21.

Disposed and compressed within catheter 10 is a filter 21. Filter 21 includes a membrane 22 disposed in a generally conical arrangement. Membrane 22 defines a plurality of apertures 23 extending therethrough. Filter 21 also includes a frame 24 which preferably is formed from a zigzag member which in a transverse cross section through housing 18 has a generally circular cross section. The collapsed diameter of frame 24 is preferably about the same but less than the inside diameter of lumen 19 at housing 18. The length of membrane 22 between frame 24 and wire 26 is preferably between about 5 mm and 50 mm, and more preferably between 10 mm and 30 mm, and most preferably approximately 20 mm. Filter membrane 22 is adhered to zigzag frame member 24 by a solvent casting method, wherein the liquid membrane polymer is dipped over the zigzag frame and allowed to cure and solidify.

Filter 21, including membrane 22 and frame 24 are attached to a wire 26 which extends the length of catheter 12. The proximal end of filter 21 is connected to wire 26 by two or more tails 28 extending from frame 24 to a stop

29. Stop 29 can be a clamp or wire winding, solder or other connector. At the distal end of filter 21, membrane 22 may be adhered to wire 26 by a suitable adhesive such as, for example, cyanoacrylates. A coil tip 30 such as one known to those skilled in the art is preferably disposed at the distal end of wire 26.

Wire 26 is preferably formed from stainless steel, NiTi alloy and/or other suitable biocompatible materials known to those skilled in the art of guidewire construction. Wire 26 can also include a radiopaque marker band or plating to aid in the placement of filter 21. Frame 24 and tails 28 are preferably formed from an NiTi alloy such as Nitinol, but can comprise stainless steel or other suitable materials. Frame 24 is preferably heat set to expand to the configuration shown in Figure 2 when exposed to approximately body temperature.

Membrane 22 of filter 21 preferably has a thickness of between 25 microns and 100 microns and most preferably about 40 microns. The filter is preferably formed from polyurethane or other biocompatible material such as, for example, polyesters or silicones. The filter can be coated with various coatings to impart various functional performance characteristics, one example being a thrombus resistant coating such as Heparin to discourage clot formation on filter 21. Apertures 23 can be drilled in a precise pattern using excimer laser or other ablation techniques or by mechanical techniques.

The size of apertures 23 can vary along the length of filter 21 for example, larger apertures may be placed more proximally and smaller apertures more distally or vice versa. The size of the apertures may transition gradually or abruptly in a proximal or distal direction. The apertures shape can vary from

circular shaped to rectangular, square, trapezoidal, oval, slit or other shape. A circular aperture may have a diameter of, for example, 100 microns whereas a slit may have a width of 100 microns and a length of 300 microns. The edges of the apertures can be mechanically or chemically chamfered, etched or polished to provide a smooth and rounded shoulder to streamline the passage of blood from within the conical shape portion of the filter to outside of the filter. To limit thrombus formation, the apertures size and design should be such that the shear forces that blood components are exposed to are appropriate while blood is passing through the filter. Thus, aperture sizes should be selected to limit stagnation and re-circulation of blood in and around the filter while the filter is in use.

Catheter 12 can be formed in two or more sections such as proximal section 14 and distal section 16. These sections can be releasably coupled together by way of a bayonet coupling 32 having a male portion 34 and female portion 35. Alternately, a threaded coupling could be used. As will be explained in more detail below by providing the ability to separate catheter 12 into several sections, catheter 12 can be used as a single operator exchange device.

In use, assembly 10 is advanced to a treatment site such as a coronary saphenous vein bypass graft by way of, for example, a femoral approach such that housing 18 and filter 21 is disposed distally of a lesion to be treated. Catheter 12 is then withdrawn distally such that filter 21 can expand in the direction shown by the arrows in Figure 2. Filter 21 should be allowed to expand such that it substantially traverses the cross sectional area of the vessel.

If catheter 12 is divided into sections such as section 14 and 16, catheter 12 can be completely removed from the body over a wire 26 having a standard guidewire length of about 180 cm for a femoral approach to a coronary artery or graft. First proximal section 14 is backed out of the body while holding the proximal end of wire 26 as coupling 32 emerges from the body. Section 14 is uncoupled from section 16 exposing wire 26 therebetween. Wire 26 disposed between section 14 and 16 can then be grasped and section 14 removed proximally from wire 26. Section 16 and housing 18 can subsequently be removed proximally from wire 26. The length of sections 14 and 16 and the length of wire 26 are preferably such that a physician can at all times during removal of catheter 12 grasp a portion of wire 26 disposed outside of the patient's body. It should be understood, however, that catheter 12 need not be a single operator exchange catheter but rather can be an over-the-wire catheter or other type as known to those skilled in the art.

Once catheter 12 has been removed from wire 26, wire 26 can be used as a guidewire for advancing surgical instruments thereover. For example, an angioplasty balloon could be advanced over wire 26 to a location just proximal of filter 21. While filter 21 is deployed, angioplasty can be performed. Plaque and thrombus dislodged by the procedure will then drift distally into filter 21. It is anticipated that other procedures will be performed in this way including, for example, atherectomy and stent placement.

Figure 3 is a side view of an alternate catheter 112 having a proximal shaft section 114 and a distal shaft section 116. Proximal shaft section 114 is

connected to distal shaft section 116 by a highly flexible or braided section 132. When catheter 112 is withdrawn in the direction of the arrow, braided section 132 is drawn tight for removal from wire 26 and filter 21 as explained above with respect to catheter 12. As proximal shaft portion 114 is withdrawn proximally, braided section 132 will be exposed outside of the body. Distal section 116 can then be advanced proximally relative to proximal section 114 as shown in Figure 4. Braided section 132 can then be collapsed to shorten the overall length of catheter 112. The length of sections 114, 116 and 132 relative to wire 26 should be such that wire 26 can be grasped by a physician at all times during removal of catheter 112.

Figure 5 is a side view of an alternate filter 121 in accordance with the present invention. Like filter 21, filter 121 includes a membrane 122 defining a plurality of apertures 123. Filter 121 also includes a conical portion formed by a portion of membrane 122 surrounding wire 26. Filter 121 also includes a generally cylindrical portion which at its proximal end is connected to a generally circular frame 124. Two or more tails 128 extend from frame 124 to wire 26. Tails 128 are attached to wire 26 at stop 29. Membrane 122 is attached to frame 124 by a solvent casting method as explained previously with respect to filter 21. A cyanoacrylate or epoxy adhesive can be used to connect the distal end of filter 121 to wire 26. The materials of construction for the filter can be selected from those described above with respect to filter 21. For example, frame 124 can be formed from NiTi alloys such as Nitinol and membrane 122 can be formed from polyurethane and treated and cut as described with respect to membrane 22 above.

Figure 6 is a cross sectional view of filter 122 taken from Figure 5. As shown in both Figures 5 and 6, filter 121 is in an expanded position. As can be seen in Figure 6, spaced at approximately 90° around frame 124 are four bending set points 125. Frame 124 can be bent at these points as described in more detail below to collapse filter 121 for delivery. Preferably, frame 124 is heat set to assume the expanded configuration shown in Figures 5 and 6 when exposed to approximately body temperature. The number of set points 125 and tails 128 can vary without deviating from the scope of the present invention.

Figure 7 is a side view of filter 121 disposed in delivery catheter housing 18. Shown in Figure 7, bending set points 125 adjacent tails 128 are disposed proximally of the other two bending set points 125. Figure 8 is a cross sectional view of housing 18 and filter 121 rotated 90° about the longitudinal axis of wire 26 from the view shown in Figure 7. By reference to both the views of Figure 7 and Figure 8, it can be appreciated that frame 124 bends proximally at the bending set points 125 connected to tails 128 and distally at the more distally disposed bending set points 125.

Figures 9-16 show various housing configurations described in the context of a delivery catheter. It can be appreciated by those skilled in the art that one or more of these housing configurations could be used for a retrieval catheter as well.

Figure 9 is a cross sectional view of an alternate housing 118 having an atraumatic distal portion 140 which tapers distally over filter 21 to a distal tip 120. Figure 10 is an end view of housing 118 of Figure 9 showing a longitudinal slit

144 extending proximally from distal end 120. Tapered portion 140 is preferably disposed over filter 120 and then heat shrunk around filter 21. Those skilled in the art will appreciate that heat shrink material such as, for example, Teflon® would be suitable for forming taper portion 140.

Once housing 118 and filter 21 are positioned distally to the treatment site, filter 21 can be deployed by withdrawing housing 118 proximally. Slit 144 will allow portion 140 to open or unwrap as portion 140 is drawn proximally over filter 21. Slit 144 as shown in Figure 10 only extends through tapered portion 140, however, a slit could extend to the proximal end of catheter 112. Those skilled in the art will appreciate that such a slit could be advantageously used to remove catheter 112 from a standard length wire 26.

Figure 11 is a cross sectional view of an alternate housing 218 having a distal end 220. The diameter of housing 218 has been set such that a portion 246 of filter 21 extends transversely over distal end 220 of housing 218. This provides a smooth atraumatic profile for advancement of housing 218 and filter 21.

Figure 12 is a cross section of yet an alternate embodiment of a housing 318 having a distal end 320 and a distal portion 340 curving transversely inward toward filter 21. The curve of distal portion 340 provides a desirably atraumatic profile for advancement of housing 318 and filter 21 to a treatment site.

Figure 13 is a cross sectional view of yet another embodiment of a housing 418. Housing 418 includes an elastomeric tapered portion 440. Tapered portion 440 of housing 418 has a distal end 420. Tapered portion 440 presents a

desirableatraumatic profile for advancement of housing 418 and filter 21 to a treatment site. Once filter 21 and housing 418 are advanced distally of a treatment site, housing 418 can be withdrawn proximally from filter 21. As housing 418 is withdrawn proximally, elastomeric portion 440 stretches transversely such that filter 21 can exit distally from an opening at distal end 420.

Figure 14 is a cross sectional view of yet alternate embodiment of a housing 518 having a distal end 520. Housing 518 is substantially similar to housing 18, except that a highly flexible distal portion 540 is disposed at distal end 520. Highly flexible portion 540 can be formed from a material such as, for example, silicone rubber.

Figure 15 is a cross sectional view of yet an alternate embodiment of a housing 618 having a distal end 620. A filter 21 is disposed therein. Filter 21 is placed on a wire 626 which extends sufficiently beyond the distal end of filter 21 and distal end 620 of housing 618 to allow a generally conical, elastomeric shell 640 to be placed over distal end 620 while being connected to wire 626. The generally conically shaped shell 640 provides a desirably tapered distal profile for advancement of housing 618 and filter 21 to a treatment site. Elastomeric shell 640 can be formed from a biocompatible material such as, for example, polyurethane or silicone rubber.

As can be seen in Figure 16, as housing 618 is withdrawn proximally from filter 21, elastomeric shell 640 will collapse around wire 626. It can be appreciated that the amount of elastic rebound, or the extent to which shell 640

collapses around wire 626 is a function of the modulus of elasticity of the material.

Figure 17 is a cross sectional view of a retrieval catheter 50 advanced on to wire 26 of a deployed filter 21. A retrieval catheter, such as catheter 50, is advanced to the treatment site to retrieve a filter 21 after an interventional procedure has been completed or the filter is no longer needed.

Catheter 50 has a housing 52 defining an inner lumen 53. Catheter 50 preferably has a shaft portion substantially similar to the embodiments described above with respect to catheter 12. Although a catheter such as a catheter 12 described above could be used to retrieve deployed filter 21, it is desirable that a retrieval catheter for filter 21 have both an atraumatic distal tip and a larger lumen for receiving a deployed filter 21. That is, lumen 53 preferably has a diameter greater than lumen 19 of housing 18. The inside diameter of lumen 53 is preferably between 3F and 7F and more preferably between 4F and 6F and, most preferably about 5F. Housing 52 has a distal end 57.

A tapered insert 58 is disposed at distal end 57. Tapered insert 58 includes two scissor-like elements 60 and 62 which generally taper in a distal direction. Elements 60 and 62 are pivotally connected to wire 26 by pivot connector 61. Disposed at the proximal end of elements 60 and 62, respectively, are insert tabs 64 and 66 disposed within an insert receiving groove 56 of housing 52. The distal end of insert 58 includes a surface 68 on element 60 and a surface 70 on element 62 defining a stop receiving groove therebetween. Catheter 50 and insert 58 can be made from biocompatible materials known to those skilled in the art of

catheter construction. Those materials include, among others those discussed above with respect to catheter 12.

Figure 18 is a view of catheter 50 and filter 21 of Figure 17, wherein filter 21 has been withdrawn proximally such that stop 29 has engaged insert 58. As can be seen in Figure 18, stop 29 has engaged surfaces 68 and 70 of insert 58, elements 60 and 62 are pivoted about pivot connector 61 in the direction shown by the arrows. This has allowed tabs 64 and 66 to be displaced from insert receiving groove 56. It has thus been possible for insert 58, as well as filter 21, to have been moved proximally

Figure 19 is yet another cross sectional view of catheter 50 and filter 21, wherein filter 21 has been partially collapsed and withdrawn into housing 52. Tabs 64 and 66 of insert 58 are engaging a stop ring 54 to limit further proximal movement of filter 21 relative to housing 52. In the configuration shown in Figure 19, housing 52 and filter 21 can be withdrawn from a patient's body proximally.

Figure 20 is a cross sectional view of an alternate embodiment of a retrieval catheter 150. Retrieval catheter 150 includes a retrieval housing 152 and shaft 151. Housing 152 defines a retrieval lumen 153, and has a distal end 157. Catheter 150 is preferably made from materials the same or similar as those used to make catheter 50. Lumen 153 is also preferably sized similarly to lumen 53.

Disposed within catheter 150 is an insert catheter 172. Insert catheter 172 extends proximally from the proximal end of catheter 150 and is longitudinally slideable therein. Insert catheter 172 includes a shaft 174 having a transversely

enlarged portion 176. Portion 176 preferably has a maximum outside diameter of approximately equal to, but less than, the inside diameter of lumen 153. Shaft 174 and portion 176 define a wire receiving lumen 178. Portion 176, as shown in Figure 20, extends distally of distal end 157 of housing 152 and includes a tapered portion 180 tapering to a distal end 181. A sheath 182 extends proximally from taper portion 180 over and around distal end 157 of housing 152 to present a smooth tapered distal profile. An alternate embodiment of catheter 172 could be made without sheath 182.

One skilled in the art would appreciate the biocompatible materials available for construction of insert 172. Tapered portion 180 should be formed from material which is relatively soft andatraumatic. Sheath 182 is preferably formed from a relatively flexible biocompatible material, which is sufficiently flexible to deform as described in more detail below.

Figure 21 is a view of catheter 150 and filter 21 of Figure 20, wherein filter 21 and insert 178 have been moved proximally such that sheath 182 has deflected in a distal direction. To complete the withdrawal of filter 21 from the vessel, insert 172 and filter 21 are moved proximally until filter 21 is collapsed and substantially drawn into housing 152.

Figure 22 is a cross sectional view of an alternate embodiment of a retrieval catheter 250 having a shaft 251 and retrieval housing 252. Housing 252 defines an inner lumen 253 and has a distal end 257. Disposed within housing 252, substantially proximally of distal end 257, is a distal bumper 286. Disposed still more proximally is a second and proximal bumper 288. Catheter 250 can be

made from materials similar to those used to construct catheter 50. The inner diameter of lumen 253 is preferably similar to that of lumen 53.

Slidably disposed within lumen 253 is a housing insert 272. Insert 272 includes an elongate portion 274 having a bumper 276 disposed at the proximal end thereof. At the distal end of elongate portion 274 is an atraumatic tip 278 which is preferably formed from a soft atraumatic material adhered to elongate portion 274. Tip 278 preferably has a tapered end 280 extending to a distal tip 281. Extending transversely from tip 278 is a friction ledge 282 which engages distal end 257 of housing 252.

In use, when it is desired to retrieve deployed filter 21, catheter 250 is advanced over wire 26 until distal tip 281 engages stop 29. Catheter 250 is then pushed against pressing stop 29 and distal tip 281. The pushing force on catheter 250 is increased until friction ledge 282 deforms allowing insert 272 to move proximally in housing 252. Bumpers 286 can limit the distal travel of insert 272, bumpers 288 limit the proximal travel of insert 272 such that filter 21 will be at least partially collapsed and withdrawn into housing 252 for withdrawal from the body.

Figure 23 is a cross sectional view of catheter 150 into which an alternate insert catheter 372 has been placed. Insert catheter 372 is similar to insert catheter 172 except that, rather than including a solid expanded portion 176, catheter 372 includes a balloon 380 disposed at the distal end of a shaft 374. An inner shaft 375 extends through shaft 374 and defines an annular inflation lumen 378 between shaft 375 and shaft 374 in fluid communication with balloon 380.

Shaft 375 also defines a wire receiving lumen 376. Balloon 380 includes a tapered distal portion 382 which tapers to a distal end 384 sealably connected to the distal end of shaft 375. Those skilled in the art of balloon catheter construction will recognize the materials available for construction of balloon catheter insert 372.

In use, balloon 380 can be inflated and disposed at distal end 157 of housing 152 for advancement over wire 26. In this configuration, balloon 380 presents a tapered atraumatic profile desirable for advancement of catheter 150 to filter 21. Balloon 380 can then be deflated and balloon insert catheter 172 can be advanced over filter 21. Catheter 150 and filter 21 can then be withdrawn proximally from the patient's body.

Figure 24 is a schematic, cross sectional view of a manifold for retrieval of a catheter 150 and balloon insert catheter 372. Manifold 700 includes a positive prep port portion 702 connected to the proximal end of catheter 152. The positive prep port portion 702 includes a positive prep port 703 in fluid communication with lumen 153 of shaft 151 of catheter 150. Positive prep portion 702 preferably includes at its distal end an interference connector 704 to connect a strain relief 706 thereto. Positive prep port portion 702 also includes a slide stop 708. One skilled in the art would recognize that manifolds can also be used for delivery catheters.

Manifold 700 includes a balloon prep portion 710 slidably disposed over positive prep portion 702 for longitudinal movement relative to portion 702. Balloon prep portion 710 includes a balloon prep port 712. Balloon insert

catheter shaft 374 is connected to balloon prep port portion 710. Balloon prep port 712 is in fluid communication with balloon inflation lumen 378. Portion 710 also includes a stop slot 714 for receipt of stop 708 and a lumen 716 for slidable receipt of positive prep portion 702. A plurality of threads 717 are disposed at the proximal end of portion 710.

A collet 718 is disposed in part within portion 710 and in part between portion 710 and a guidewire clamp 720. Clamp 720 includes a plurality of threads 721 engageable with threads 717 of portion 710. Clamp 720 includes a guidewire prep port 722. Collet 718 can be tightened or loosened to hold guidewire 26 therein by threading or unthreading clamp 720 from portion 710. Collet 718 is shown clamped on wire 26 in both Figures 24 and 25.

In use, balloon 780 can be advanced to distal end 157 of catheter 150 when portion 710 is advanced distally over positive prep portion 702 as shown in Figure 24, such that stop 708 is at the proximal end of stop slot 714. Balloon 708 can be inflated by way of inflation port 712. In this configuration, catheter 150 and insert 372 can be advanced over wire 26 to retrieve filter 21. Then collet 718 can be tightened to hold wire 26. Positive prep portion 702 is then pushed distally to capture filter 21. This will draw filter 21 into housing 152 of Figure 23. Balloon 380 can be deflated prior to moving positive prep portion 702 distally. Stop 708 will be at the distal end of stop slot 714, as shown in Figure 25, after housing 152 is moved over filter 21. Contrast media, saline or other fluids may be infused through positive prep port 703 as needed. Fluids could also be withdrawn through 703, if necessary. In the above embodiments, it has been shown that filter 21

remains stationary, while the various housing embodiments have been described as being advanced over the stationary filter 21 in order to retrieve said filter. Retrieving filter 21 into the housing, although a possible method of retrieval, is not preferred because of potential injury to the vessel lumen wall as the filter is dragged therein.

Figure 26 is a cross sectional view of an alternate embodiment of a manifold 800. Manifold 800 includes a handle 802 including a distal arm 803 from which extends an interference connector 804 to connect a strain relief 806 thereto. Shaft 151 of catheter 150 is connected to arm 803. Handle 802 includes a proximal arm 805. Extending between proximal arm 805 and distal arm 803 is a slide rail 807. Mounted on slide rail 807 is a balloon prep portion 810. Balloon prep portion 810 includes a balloon prep port 812 in fluid communication with lumen 378 at catheter 372. Shaft 374 is connected to balloon prep portion 810. Wire 26 extends through portion 810 which is sealed around wire 26 by seal 813. Balloon prep portion 810 defines a rail lumen 816 such that balloon prep portion 810 is slidable longitudinally over rail 807. Proximal arm 805 also includes a threadable connector portion 817 threadably connected to a guidewire clamp 820. A collet 818 is disposed between arm 805 and clamp 820 which is threadably connected by threads 821 to threads 817. Clamp 820 includes a guidewire prep port 822.

In use, balloon 780 can be advanced to the distal end 157 of catheter 150 by advancing portion 810 distally over rail 807 to distal arm 803. Balloon 708 can be inflated by way of inflation port 812. In this configuration, catheter 150

and insert 372 can be advanced over wire 26 to retrieve filter 21. Collet 818 can then be tightened to hold wire 26. Handle 802 is then pushed distally to capture filter 21. This will draw filter 21 into housing 152. Balloon 380 can be deflated prior to moving handle 802 distally. Portion 810 will then be repositioned proximally adjacent arm 805. As described with respect to manifold 700, it is also possible to hold handle 802 stationary and move wire 26 distally to draw filter 21 into housing 152, however, this method is not preferred because of potential injury to the vessel lumen wall as the filter is dragged proximally.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size and ordering of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A filter assembly, comprising:

a catheter including an elongate shaft having a proximal end and a distal end and a housing disposed at the distal end, the housing having a distal end; an elongate wire extending at least in part through the catheter, the wire having a proximal end and a distal end; and a filter connected to the wire proximate the distal end of the wire, and the filter being disposed in a position at least in part within the housing.

2. The filter in accordance with claim 1, wherein the filter is moveable between the position at least in part inside the housing and a position outside the housing.

3. The filter in accordance with claim 2, further comprising a housing insert disposed within the housing and extending distally therefrom when the filter is in the position outside the housing.

4. The filter assembly in accordance with claim 3, wherein the insert tapers distally.

5. The filter assembly in accordance with claim 3, wherein the insert is releasably connected to the distal end of the housing.

6. The filter assembly in accordance with claim 3, wherein the insert includes a balloon.

7. The filter assembly in accordance with claim 6, further comprising a manifold disposed at the proximal end of the shaft, the manifold including a positive prep port, a guidewire port and balloon inflation port.

8. The filter assembly in accordance with claim 3, wherein the insert includes a flap which extends transversely over the distal end of the housing.

9. The filter assembly in accordance with claim 1, wherein the distal end of the housing is heat shrunk around the at least a portion of the filter.

10. The filter assembly in accordance with claim 1, wherein a portion of the filter extends transversely of the distal end of the housing.

11. The filter assembly in accordance with claim 1, wherein the distal end of the housing extends transversely inward toward the filter.

12. The filter assembly in accordance with claim 1, wherein the distal end of the housing includes an elastomeric sheath which tapers distally.

13. The filter assembly in accordance with claim 1, wherein the distal end of the housing is atraumatic.

14. The filter assembly in accordance with claim 1, further comprising a collapsible shell connected to the wire and disposed substantially distally of the filter.

15. The filter assembly in accordance with claim 1, wherein the wire extends distally of the filter.

16. The filter assembly in accordance with claim 15, further comprising a spring tip at the distal end of the wire.

17. The filter assembly in accordance with claim 1, wherein the elongate shaft includes at least one releasable coupling for coupling a distal portion of the shaft to a proximal portion of the shaft.

18. The filter assembly in accordance with claim 17, wherein the coupling includes a bayonet fastener.

19. The filter assembly in accordance with claim 17, wherein the coupling includes a threaded fastener.

20. The filter assembly in accordance with claim 1, wherein the elongate shaft includes a longitudinally collapsible member.

21. The filter assembly in accordance with claim 20, wherein the longitudinally collapsible member includes a braid.

22. The filter assembly in accordance with claim 1, wherein the catheter is a filter retrievable catheter.

23. The filter assembly in accordance with claim 1, wherein the catheter is a filter delivery catheter.

24. A guidewire assembly, comprising:
an elongate guidewire having a proximal end and a distal end; and
a filter disposed at the distal end of the wire, the filter including an expandable frame and a filter membrane.

25. The guidewire assembly in accordance with claim 24, wherein the wire extends distally of the filter.

26. The guidewire assembly in accordance with claim 25, further comprising a spring tip at the distal end of the wire.

27. The guidewire assembly in accordance with claim 24, wherein the frame includes a NiTi alloy.

28. The guidewire assembly in accordance with claim 24, wherein the membrane surrounds a portion of the wire.

29. The guidewire assembly in accordance with claim 24, wherein the filter membrane portion of the filter tapers distally.

30. The guidewire assembly in accordance with claim 24, wherein the membrane includes polyurethane.

31. The guidewire assembly in accordance with claim 24, wherein the membrane defines a plurality of apertures.

32. A method of retrieving and deploying an intravascular filter, comprising the steps of:

providing a catheter having an elongate shaft having a distal end and a proximal end, and a housing disposed at the distal end, and providing a filter disposed on an elongate wire;

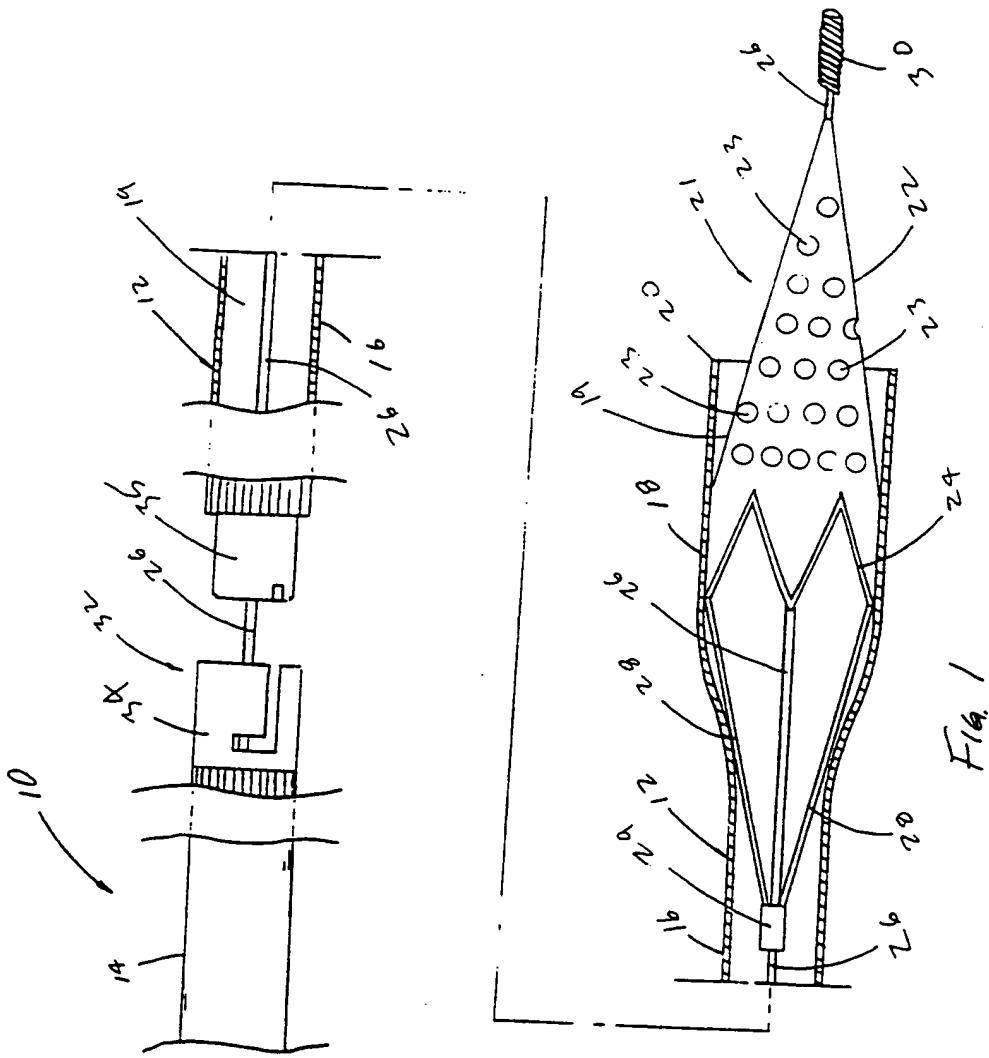
placing the filter in the housing;

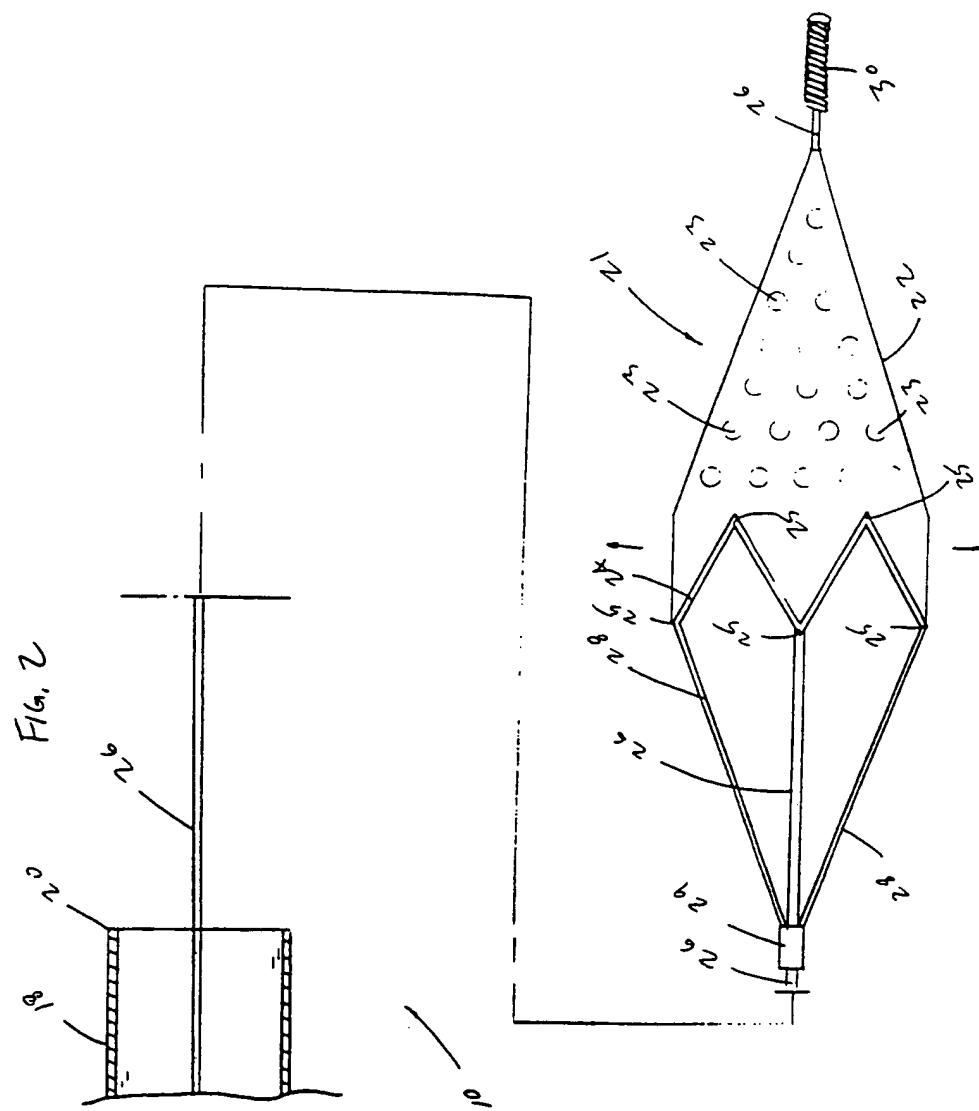
advancing the filter and housing to a treatment site;

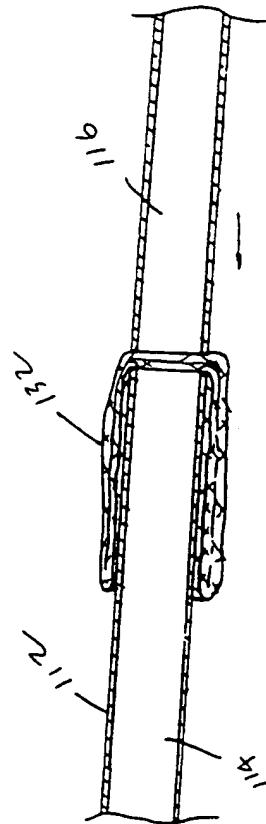
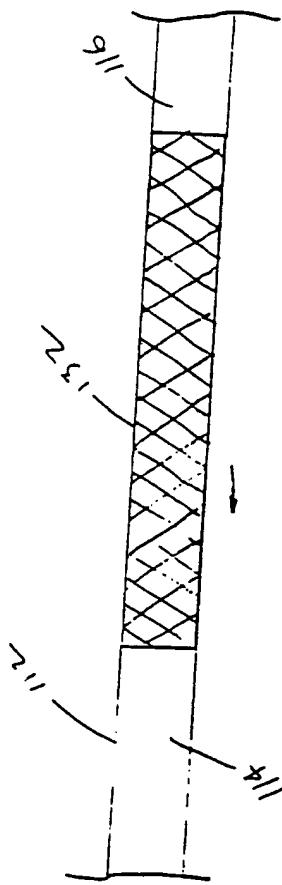
removing the filter from the housing;

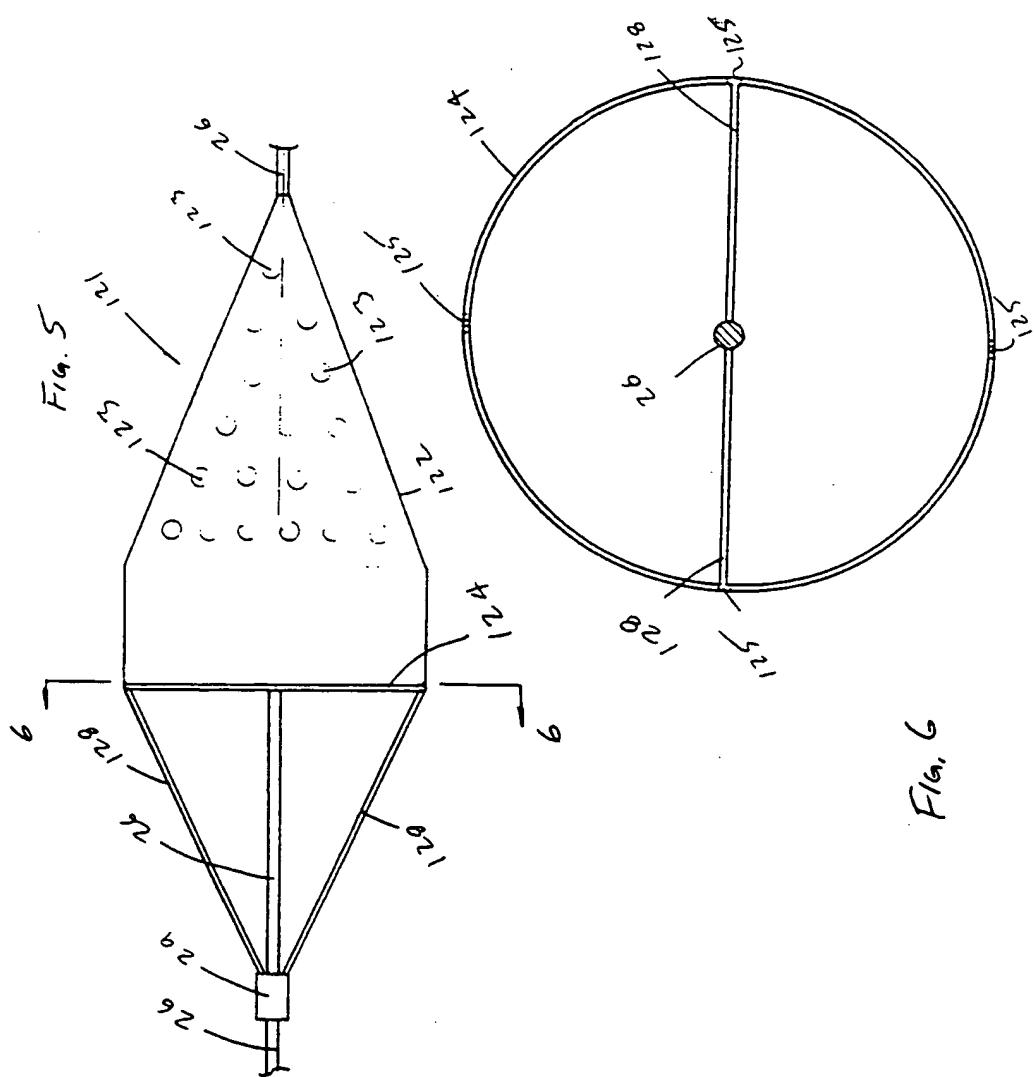
replacing the filter in the housing; and
withdrawing the filter and housing from the treatment site.

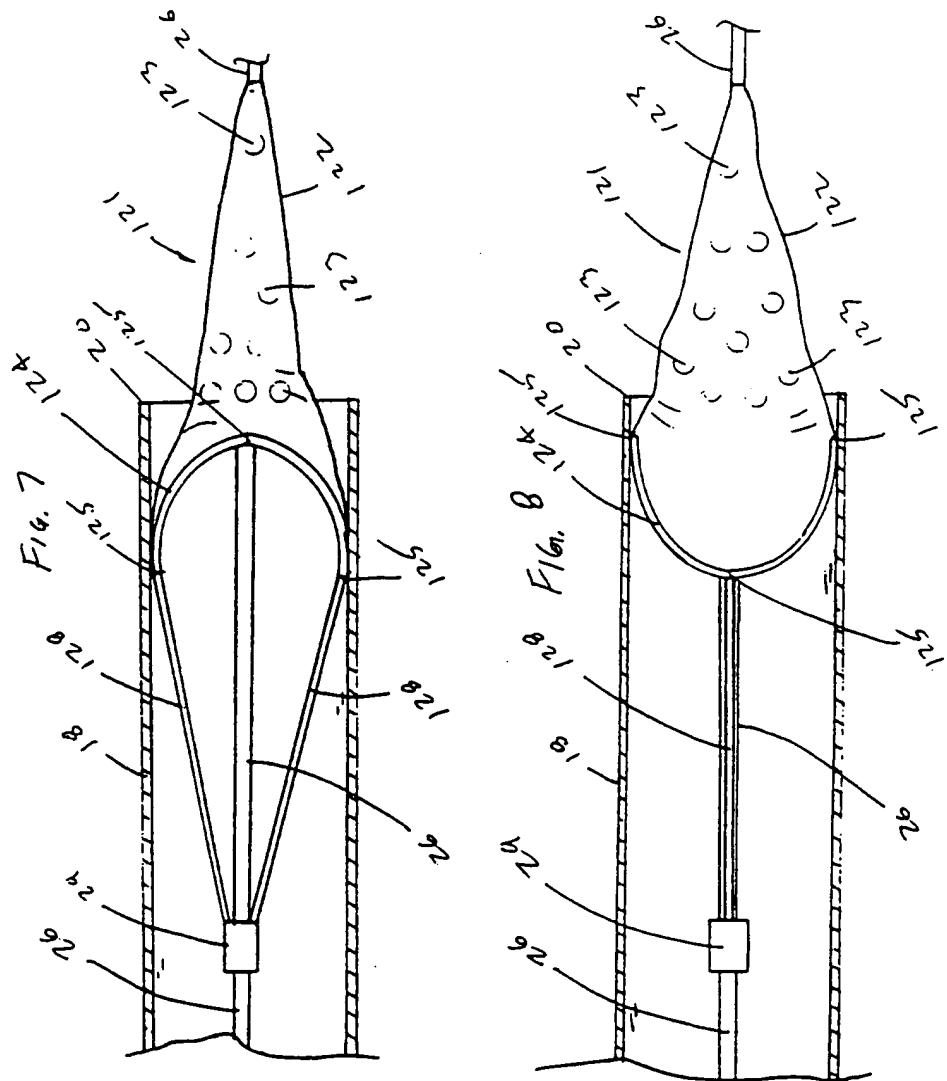
33. A method in accordance with claim 32, wherein the filter is placed in the housing by moving the housing distally to capture the filter.











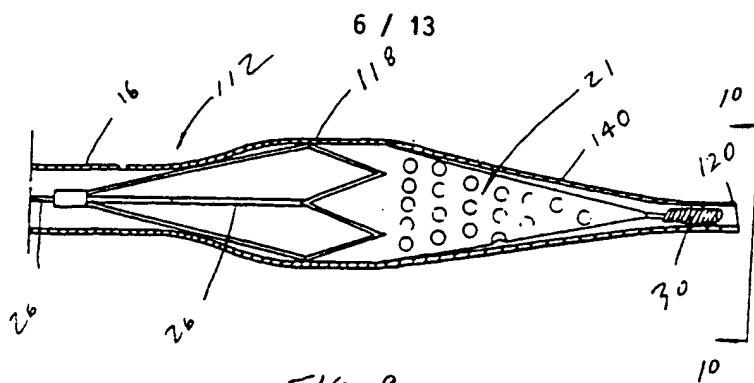


FIG. 9

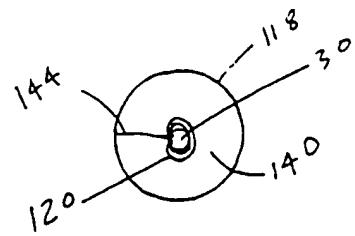


FIG. 10

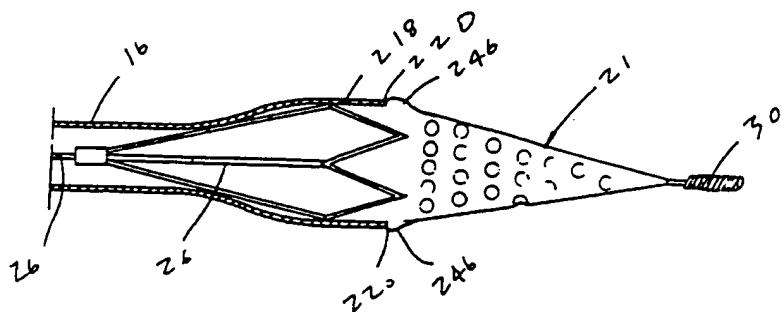


FIG. 11

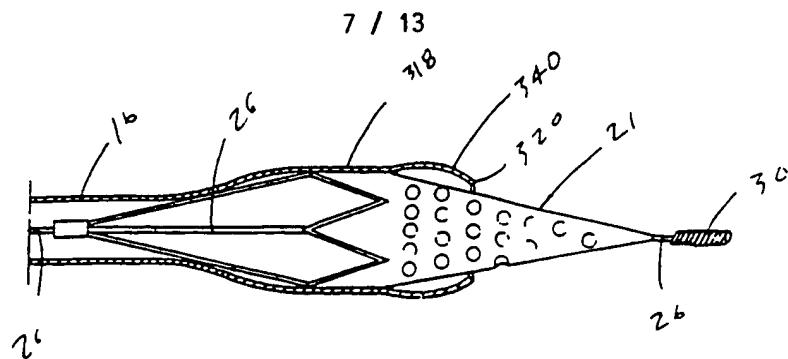


FIG. 12

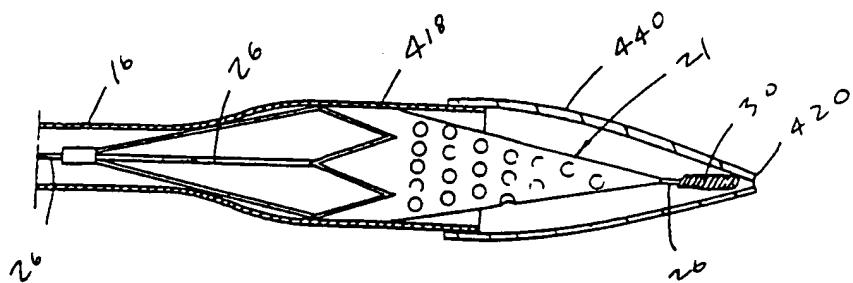


FIG. 13

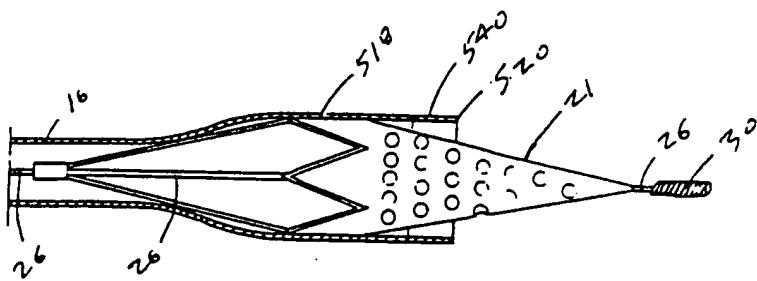


FIG. 14

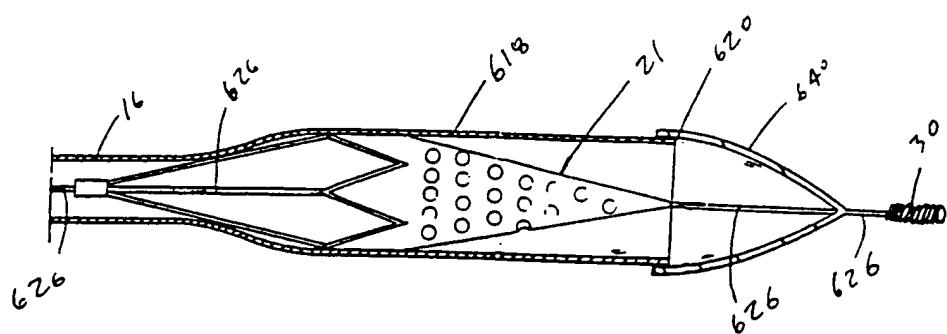


FIG. 15

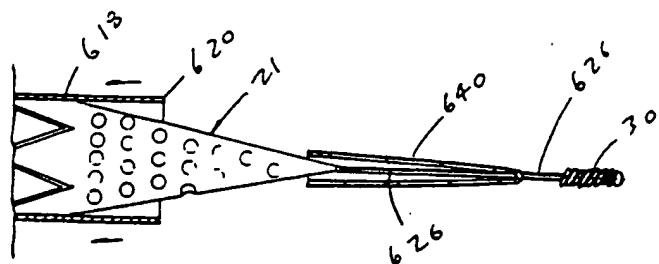
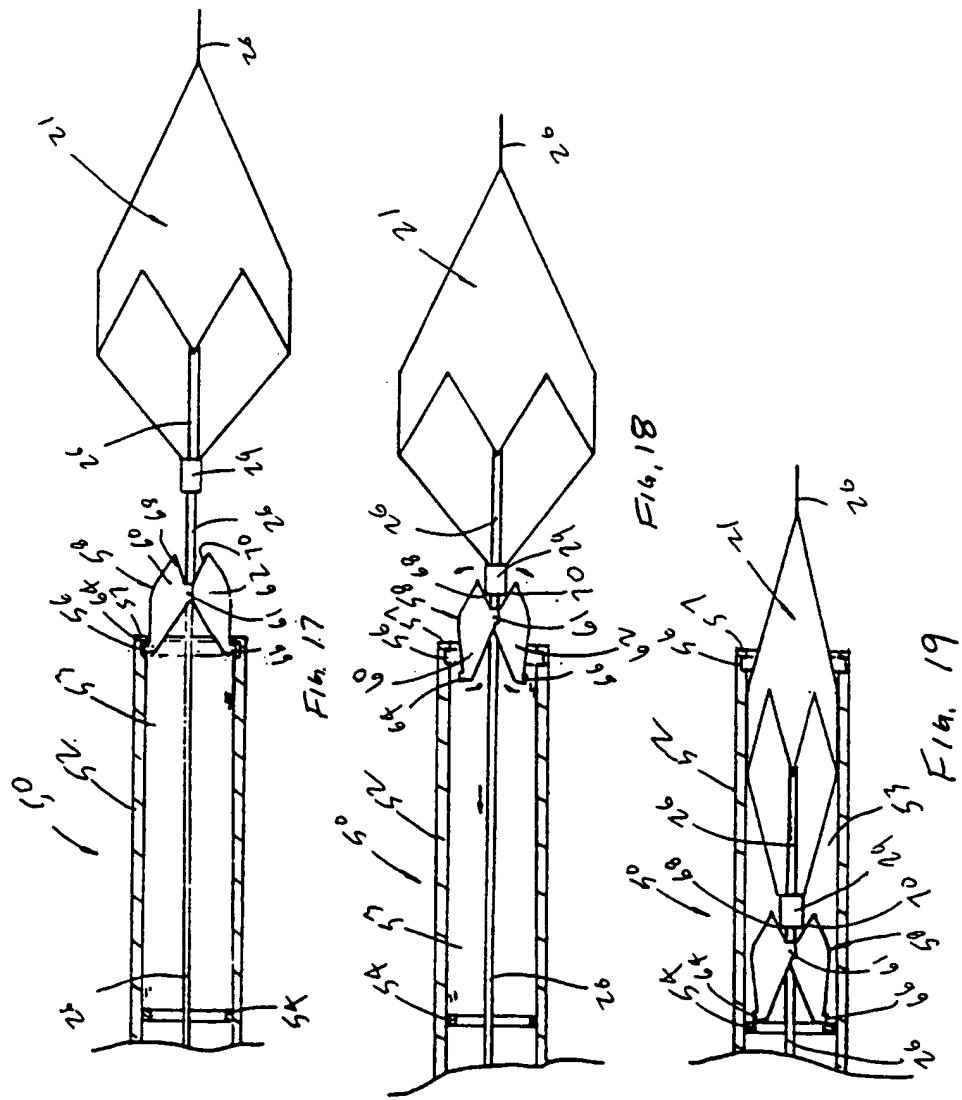


FIG. 16



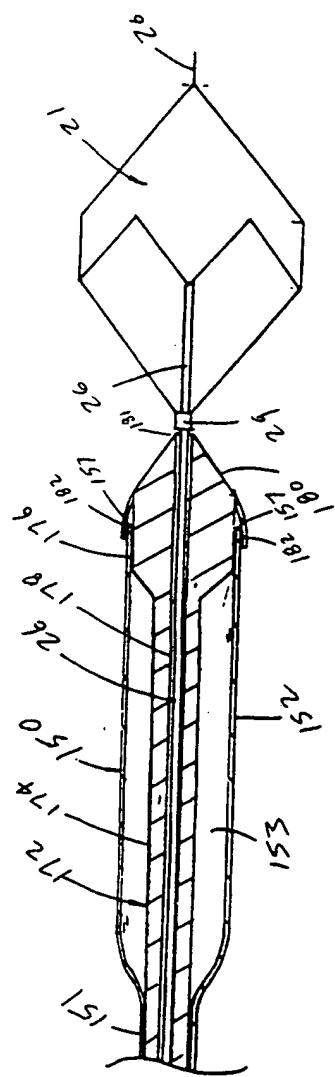


Fig. 20

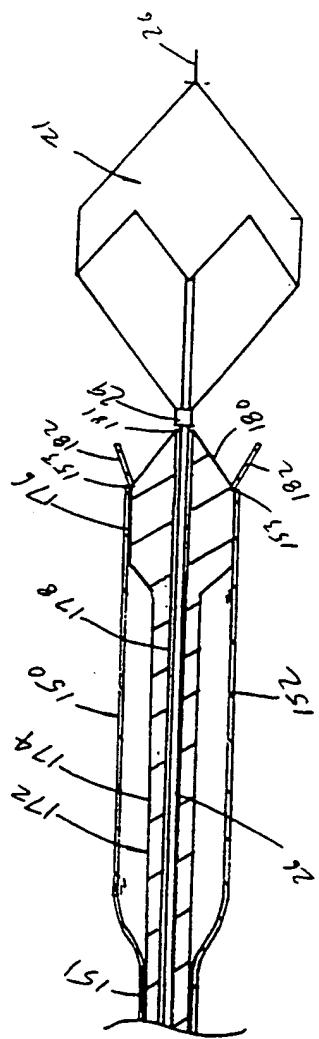
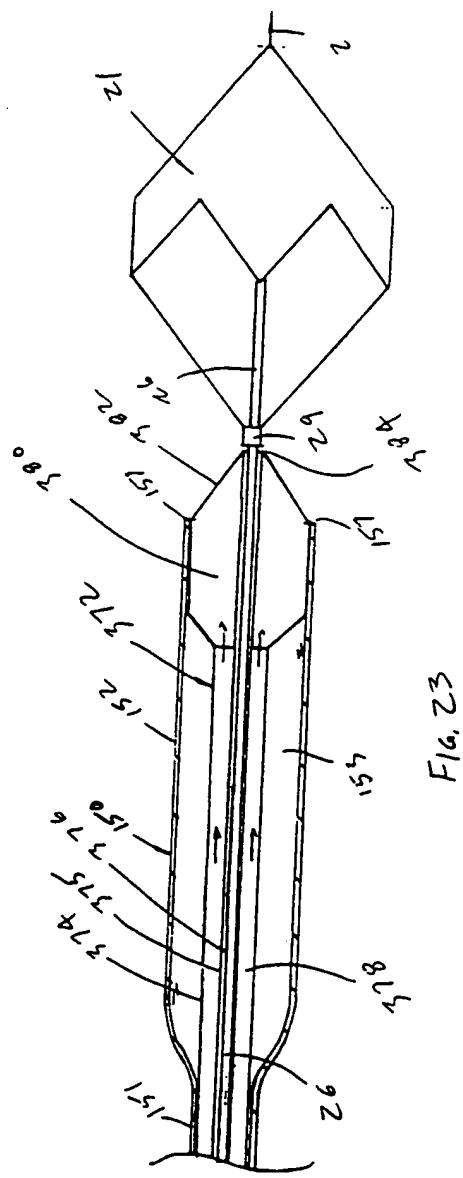
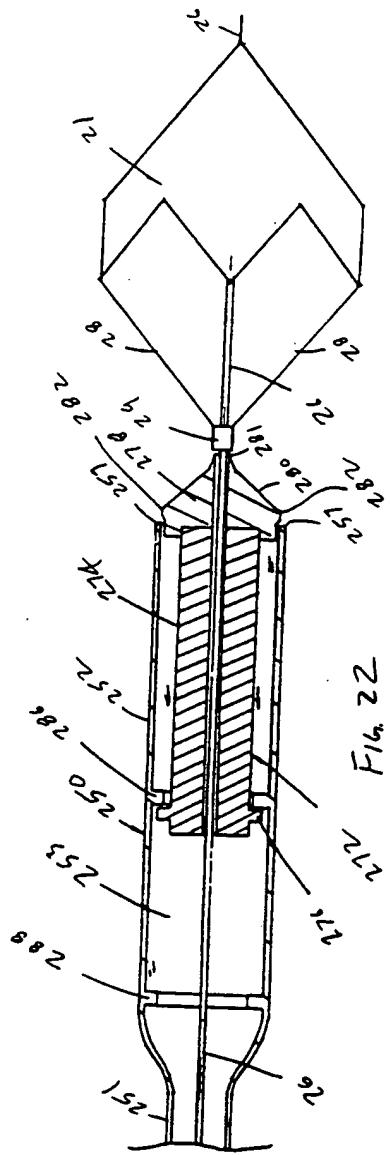
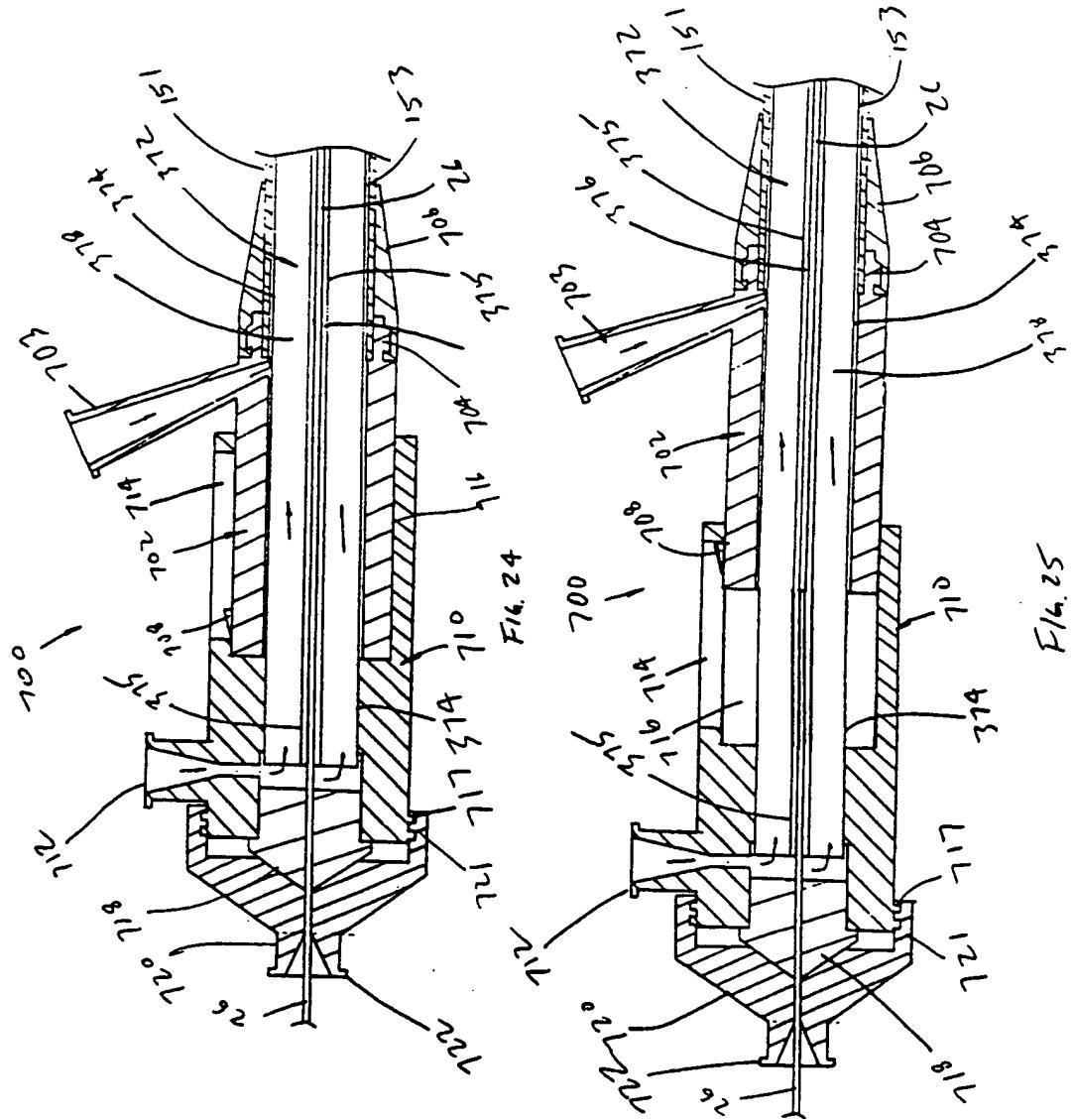


Fig. 21

11 / 13





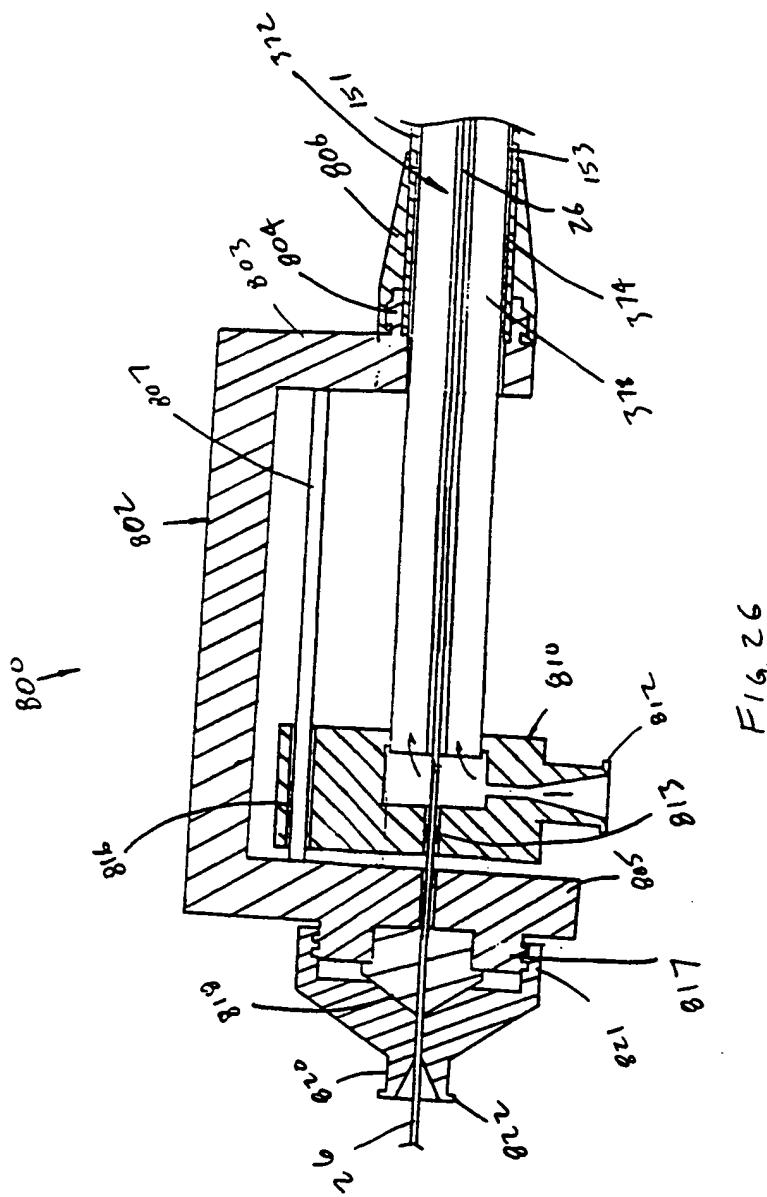


Fig. 26

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/04975

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	<p>WO 99 44542 A (SCIMED LIFE SYSTEMS INC) 10 September 1999 (1999-09-10)</p> <p>figures 5-11, 13-15, 17-24 page 8, line 21 -page 10, line 2 page 11, line 3 -page 12, line 32 page 15, line 3 -page 23, line 1</p> <p>---</p> <p>US 5 695 519 A (BALL GARY ET AL) 9 December 1997 (1997-12-09)</p> <p>figures 1-5 column 2, line 62 -column 3, line 43 column 4, line 27 - line 47</p> <p>---</p> <p>---</p> <p>-/-</p>	1-5, 15, 22-25, 27-31
X		24, 25, 27-29, 31
A		1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

6 July 2000

17/07/2000

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Mary, C

1

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/04975

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 33443 A (YADAV JAY S ;ANGIOGUARD INC (US)) 6 August 1998 (1998-08-06) page 5, line 29 -page 11, line 30 claims 1,2	24
A	---	1
P,X	US 5 989 281 A (BARBUT DENISE ET AL) 23 November 1999 (1999-11-23) figures 1-22 column 9, line 22 - line 48 column 14, line 64 -column 15, line 46 column 15, line 57 -column 16, line 31	1,2,24
A	---	3-7, 17-19
P,X	US 5 951 585 A (CATHCART BRUCE C ET AL) 14 September 1999 (1999-09-14) figures 1-9 column 5, line 56 -column 6, line 11	1,2,17, 24
A	---	18,19
A	US 5 421 832 A (LEFEBVRE JEAN-MARIE) 6 June 1995 (1995-06-06) claims 1,2; figures 1,2,4 column 3, line 37 - line 52 column 3, line 60 -column 4, line 11 claim 1	1,12,13, 24
P,A	US 5 954 745 A (KAMM ROGER ET AL) 21 September 1999 (1999-09-21) figures 1A-11 column 4, line 53 -column 6, line 8 column 7, line 60 -column 8, line 22 claims 1-31	1-3,6,7, 24

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/04975

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
WO 9944542	A 10-09-1999	NONE			
US 5695519	A 09-12-1997	NONE			
WO 9833443	A 06-08-1998	AU 6052798 A		25-08-1998	
		CA 2250777 A		06-08-1998	
		EP 0938276 A		01-09-1999	
US 5989281	A 23-11-1999	US 5769816 A		23-06-1998	
		AU 7119298 A		11-11-1998	
		EP 0975384 A		02-02-2000	
		WO 9846297 A		22-10-1998	
		AU 7605396 A		29-05-1997	
		EP 0956074 A		17-11-1999	
		WO 9717100 A		15-05-1997	
		US 5980555 A		09-11-1999	
US 5951585	A 14-09-1999	US 5681347 A		28-10-1997	
		CA 2221262 A		28-11-1996	
		EP 0835150 A		15-04-1998	
		WO 9637251 A		28-11-1996	
US 5421832	A 06-06-1995	FR 2655533 A		14-06-1991	
		AT 156992 T		15-09-1997	
		CA 2029280 A		14-06-1991	
		DE 69031304 D		25-09-1997	
		DE 69031304 T		18-12-1997	
		DK 437121 T		06-04-1998	
		EP 0437121 A		17-07-1991	
		EP 0771549 A		07-05-1997	
		EP 0771550 A		07-05-1997	
		ES 2104595 T		16-10-1997	
		GR 3025263 T		27-02-1998	
		JP 4126161 A		27-04-1992	
US 5954745	A 21-09-1999	EP 0981308 A		01-03-2000	
		WO 9851237 A		19-11-1998	

BEST AVAILABLE COPY

THIS PAGE BLANK (USPTO)